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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

MUTUAL PHARMACEUTICAL COMPANY,
INC., et al.,

Plaintiffs,

v.

WATSON PHARMACEUTICALS, INC., et
al.,

Defendants.

WEST-WARD PHARMACEUTICAL CORP.,

Counterclaimant,

v.

MUTUAL PHARMACEUTICAL COMPANY,
INC., et al.,

Counterdefendants.

Civil Action No. 09-5421(GEB)(TJB)

**MEMORANDUM IN SUPPORT OF
PLAINTIFFS' MOTION TO
DISMISS WEST-WARD'S FIRST
AMENDED COUNTERCLAIM**

Judge: Hon. Garrett E. Brown
Date: April 19, 2010
Time: 10:00 a.m.
Dept: 4E

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I. INTRODUCTION

West-Ward Pharmaceutical Corp.’s (“West-Ward”) First Amended Counterclaim (“FAC”) alleges five causes of action against counterdefendants Mutual Pharmaceutical Company, Inc., AR Scientific, Inc. and AR Holding Company, Inc. (collectively, “Mutual”): 1) tortious interference with contractual relations; 2) tortious interference with prospective economic advantage; 3) false advertising under the Lanham Act; 4) unfair competition under the Lanham Act; and 5) common law unfair competition. However, the FAC does not identify a single third party, contract, or prospective contractual partner with which Mutual allegedly interfered. Nor does it allege that Mutual’s acts caused a breach of any contractual provision. Rather, it seeks to hold Mutual liable for providing relevant consumers *truthful publicly available* information about West-Ward’s dangerous and illegal colchicine products.

Knowing that it will eventually be forced to halt its unlawful advertising and promotion of its unapproved colchicine products, West-Ward filed its FAC in a transparent effort to create a smokescreen to distract attention from its illicit conduct. But West-ward does not come close to pleading the required elements of any of its purported claims. Instead of identifying the specific actual or prospective contractual relationships at issue and the parties to them, or specifying how such relationships have actually been impaired, West-Ward meekly points to “various contractual relationships” and implies—but does not allege—that its customers were somehow bound to purchase West-Ward’s unapproved colchicine products, even after the Food and Drug Administration (“FDA”) determined they were “*not generally recognized as safe and effective for their labeled uses.*” Exhibit 1, FDA Warning Letter to Sunrise Pharmaceutical, Inc., at p. 3; *see also* Exhibit 2, FDA Warning Letter to Concord Laboratories, Inc., at p. 2.¹ West-Ward also

¹ “Generally, in ruling on a motion dismiss, a district court relies on the complaint, attached exhibits, and *matters of public record.*” *Sands v. McCormick*, 502 F.3d 263, 268 (3d Cir. 2007). The FDA’s Warning letter to Sunrise Pharmaceutical, Inc. is publicly available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm197966.htm>, and the FDA’s Warning letter to Concord Laboratories, Inc. is publicly available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm075988.htm>. Therefore, the Court may properly consider these letters, which are provided as Exhibits 1 and 2 to the Declaration of Nathaniel R. Cooper for the Court’s convenience.

fails to identify a single false statement on which to base its Lanham Act claims, and alleges a common law unfair competition claim that is expressly precluded by New Jersey law.

For these reasons the Court should dismiss the FAC pursuant to Federal Rule of Civil Procedure 12(b)(6).

II. STATEMENT OF FACTS

Mutual is the only manufacturer approved by the FDA to manufacture and market products containing colchicine as the single active ingredient.² Nevertheless, West-Ward continues to illegally market, advertise and promote colchicine products that include improper dosing guidelines and fail to warn consumers about potentially serious drug-drug interactions. As alleged in Mutual's complaint, originally filed in the United States District Court for the Central District of California ("Central District"), West-Ward's continued advertising and marketing practices are causing consumer confusion and ongoing irreparable harm to Mutual.

In response to Mutual's complaint, West-Ward filed a counterclaim against Mutual for intentional interference with contractual relations. Mutual moved to dismiss West-Ward's counterclaim on the grounds that it failed to identify a single party or contract with which Mutual allegedly interfered. Prior to ruling on Mutual's motion to dismiss, the Central District transferred this case to the District of New Jersey. This Court then denied Mutual's motion *without prejudice*, because it was unclear whether New Jersey or California law applied to West-Ward's counterclaim, and the fact-intensive choice of law analysis was inappropriate at the time. *See* Memorandum Opinion³ at 16.

West-Ward filed its FAC with this Court on February 25, 2010 and thereby conceded that New Jersey law applies to its state common law claims.^{4 5} Rather than bolster its interference

² The FDA has approved another drug product containing probenecid and colchicine in a fixed combination, but Mutual is the only company with FDA approval for a drug containing colchicine as the sole active ingredient. For purposes of convenience, the term "colchicine products" as used herein shall refer only to drug products containing colchicine as the sole active ingredient.

³ This Court's February 8, 2010 Memorandum Opinion, Docket No. 208.

⁴ It is well established that, "[w]hen a pleading is amended, the original pleading ceases to be part of the record." *See, e.g., Campbell v. Haverhill*, 155 U.S. 610, 613 (1895). Therefore, because a federal court in a diversity case applies the same law as would a court of the state in

allegations in response to Mutual's initial motion to dismiss or this Court's Memorandum Opinion, West-Ward reproduces the vague allegations regarding Mutual's alleged interference with unspecified "various contractual relationships," and adds four new causes of action: tortious interference with prospective economic advantage, false advertising under the Lanham Act, unfair competition under the Lanham Act, and common law unfair competition. The FAC still fails to identify a single contract, contractual partner or prospective contractual partner with which Mutual allegedly interfered, fails to allege that Mutual's actions caused the breach of any contractual provision, and fails to plead the falsity of any of Mutual's alleged statements.

III. LEGAL STANDARD

Upon motion, a complaint may be dismissed when a plaintiff's allegations fail to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). When considering a motion to dismiss a complaint under Rule 12(b)(6), "the Court is required to accept all of the allegations contained therein and all inferences arising therefrom as true." *Storis, Inc. v. GERS Retail Systems, Inc.*, 1995 U.S. Dist. LEXIS 7614, at *4 (D.N.J. May 31, 1995).

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949 (2009) (internal quotations omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*

For the reasons discussed below, West-ward's FAC does not comply with the notice pleading standard of Fed. R. Civ. P. 8(a)(2), which requires a "short and plain statement of the claim showing that the pleader is entitled to relief" in order to "give the defendant fair notice of what the ... claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

which the district court is located, New Jersey law applies to the FAC. *See, e.g., Erie R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938).

⁵ Furthermore, West-Ward previously urged in its December 10, 2009 Motion for Judgment on the pleadings that New Jersey law applies to Mutual's Lanham Act claims. *See* Docket No. 196. It therefore cannot reasonably dispute that the same law applies to the FAC.

Furthermore, West-Ward “must plead its Lanham Act claims with more particularity than traditional notice pleading under *Rule 8* but something less than the specificity of *Rule 9*.” *Trans USA Prods. v. Howard Berger Co.*, 2008 U.S. Dist. LEXIS 25370, at *12-13 (D.N. J. Mar. 28, 2008) (emphasis in original). It fails to do so.

IV. ARGUMENT

A. West-Ward Fails to State a Claim for Tortious Interference with Contractual Relations.

In order to state a claim for intentional interference with contractual relations, West-Ward must plead:

(1) actual interference with a contract; (2) that the interference was inflicted intentionally by a [counter]defendant who is not a party to the contract; (3) that the interference was without justification; and (4) that the interference caused damage.

Dello Russo v. Nagel, 358 N.J. Super. 254, 268 (N.J. Super. Ct. App. Div. 2003); *see also* Memorandum Opinion at 16. West-Ward fails to plead the first and third elements of this cause of action, and therefore the Court should dismiss its claim under Rule 12(b)(6).

1. West-Ward Fails to Allege Actual Interference With a Contract.

a. West-Ward Does Not Identify Any Specific Contracts or Contractual Parties.

In order to plead the first element of tortious interference with contractual relations under New Jersey law—actual interference—West-Ward must “allege the existence of a *specific* contract that was interfered with” by Mutual. *Storis, Inc.*, 1995 U.S. Dist. LEXIS 7614, at *15-16 (emphasis added) (dismissing claim for tortious interference with contract where complaint failed to identify any specific customer contracts with which defendant interfered but merely alleged generally that defendant interfered with plaintiff’s business relationships); *see also Only v. Ascent Media Group, LLC*, 2006 U.S. Dist. LEXIS 72676, at *28 (D.N.J. Oct. 5, 2006) (refusing to grant plaintiff leave to amend complaint to add tortious interference claim because “the proposed amended pleadings do not identify existing contracts ... with the *required*

specificity”) (emphasis added); *Commerce Ins. Servs. v. Szczurek*, 2006 U.S. Dist. LEXIS 515, at *26-27 (D.N.J. Jan 6, 2006) (dismissing claim for tortious interference with contractual relations where the complaint failed to “identif[y] exisiting contracts”). West-Ward fails to do so.

The FAC does not identify a single one of West-Ward’s purported contractual partners by name. Nor does it identify any specific contract or the terms thereof. West-Ward’s sole charging allegation is that it “has valid contractual relationships with various purchasers of prescription drugs, including pharmacies and wholesale purchasers.” FAC at ¶ 16. A nearly identical formulation has previously been rejected by Federal District Courts sitting in New Jersey. *See Only*, 2006 U.S. Dist. LEXIS 72676, at *28 (denying plaintiff leave to amend complaint to add a tortious interference claim where plaintiff’s proposed amendments “generally allege[d] that he ‘had valid contractual relationships ... with others,’” for failure to “identify existing contracts ...with the required specificity”); *c.f. Floorgraphics, Inc. v. News Am. Mktg. In-Store Servs.*, 2006 U.S. Dist. LEXIS 70834, at *16 (D.N.J. Sept. 29, 2006) (denying defendant’s motion to dismiss because plaintiff had “identified many [customers] by name,” but ordering plaintiff “to amend the Complaint so as to *identify the contracts* allegedly interfered with by Defendant”) (emphasis added). West-Ward’s vague allegations fail to plead actual interference as a matter of law.

b. West-Ward Does Not Allege Loss or Breach of Any Contract.

In order to plead actual interference under New Jersey law, West-Ward must allege “interference result[ing] in a *breach or loss of the contract*.” *DiGiorgio Corp. v. Mendez & Co., Inc.*, 230 F. Supp. 2d (D.N.J. 2002) (“[O]ne interferes with a contract only where he causes a party not to perform under it.”) (citing *Velop, Inc. v. Kaplan*, 301 N.J. Super. 32, 39 (N.J. Super. Ct. App. Div. 1997)); *see also Floorgraphics, Inc.*, 2006 U.S. Dist. LEXIS 70834, at *13 (listing “loss or breach of a contract as a result” of defendant’s interference as an element of tortious interference with contractual relations). To satisfy this element, West-Ward must identify a “*specific contractual provision*” and allege a breach of that provision. *Matrix Essentials, Inc. v. Cosmetic Gallery, Inc.*, 870 F. Supp. 1237, 1247 (D.N.J. 1994) (emphasis added) (“A plaintiff

may not maintain a tortious interference action where there is no specific contractual provision barring the behavior at issue.”). West-Ward fails to do either.

The FAC alleges that West-Ward “has valid contractual relationships with various purchasers of prescription drugs” (FAC at ¶ 16), and that “Mutual’s actions have induced medical professionals, pharmacists and other purchasers of colchicine tablets not to prescribe, recommend or purchase West-Ward’s tablets” (*Id.* at ¶ 23). But West-Ward does not identify any “specific contractual provisions,” nor does it allege that any contracts were breached as a result of Mutual’s actions. *Matrix Essentials, Inc.*, 870 F. Supp. at 1247. The implication of West-Ward’s allegations is that its unspecified contractual partners were *required* to buy their colchicine from West-Ward, and, as a result, breached their contracts by “not ... prescrib[ing], recommend[ing] or purchas[ing] West-Ward’s [colchicine] tablets.” FAC at ¶ 23. However, if this is the case, why hasn’t West-Ward alleged it?⁶

Because West-Ward has failed identify any contractual provisions or allege that they were breached as a result of Mutual’s actions, its claim should be dismissed under Rule 12(b)(6).

2. West-Ward Fails to Plead Absence of Justification.

West-Ward also fails to plead the third element of tortious interference with contractual relations—that the interference was without justification. *See Dello Russo*, 358 N.J. Super. at 268. It is well established that “a party may not be held liable for tortious interference for merely providing truthful information to one of the contracting parties.” *Luttman v. Tiffany & Co.*, 2009

⁶ Perhaps because an exclusive dealing provision would necessarily require medical professionals and pharmacists to subjugate their own professional judgment to their contract with West-Ward, in violation of their legal duties to “act with that degree of care, knowledge, and skill ordinarily possessed and exercised in similar situations by the average member of the profession practicing in the field,” and, therefore would likely be void under New Jersey law. *Aiello v. Muhlenberg Reg’l Med. Ctr.*, 733 A.2d 433, 437 (N.J. 1999); *see also Schueler v. Strelinger*, 204 A.2d 577, 585 (N.J. 1964) (“A physician must be allowed a wide range in the reasonable exercise of judgment. He is not guilty of malpractice so long as he employs such judgment, and that judgment does not represent a departure from the requirements of accepted medical practice, or does not result in failure to do something accepted medical practice obligates him to do, or in the doing of something he should not be measured by the standard above stated.”). Moreover, its difficult to imagine that such a contract would require third parties to continue to purchase an *illegal* drug from West-Ward, even after the FDA has determined the drug is no longer safe and effective. *See Exhibit 1*, at p. 3; *see also Exhibit 2*, at p. 2.

U.S. Dist. LEXIS 5026, at *7 (D.N.J. Jan. 26, 2006); *see also* *C.R. Bard, Inc. v. Wordtronics Corp.*, 235 N.J. Super. 168, 173-74 (N.J. Sup. Ct. Law. Div. 1989) (“It is not improper to give truthful information to a customer about someone else’s product and this is so even if the purpose is to interfere with an existing or prospective contractual relationship.”).

Here, all of Mutual’s purported statements which allegedly interfered with West-Ward’s contractual relationships involved true, publicly available information. West-Ward alleges that “Mutual falsely represented that the integrity of its product could be trusted more than West-Ward’s product.” FAC at ¶ 19. As a matter of public record, the FDA has stated that unapproved colchicine tablets—such as West-Ward’s (FAC at ¶ 9)—are “*not generally recognized as safe and effective for their labeled uses.*” Exhibit 1, at p. 3; *see also* Exhibit 2, at p. 2. Mutual’s colchicine tablets, on the other hand, *have been approved* by the FDA. FAC at ¶¶ 2, 9. Thus, to the extent that Mutual allegedly represented that “the integrity of its product could be trusted more than West-Ward’s product” (FAC at ¶ 19)—which Mutual denies—it was justified in providing this truthful publicly available information about West-Ward’s unapproved and illegal colchicine products to potential purchasers.

Because Mutual’s alleged statements were true, West-Ward’s claim for intentional interference with contractual relations should be dismissed as a matter of law. *See Luttmann*, 2009 U.S. Dist. LEXIS 5026, at *7 (dismissing claim for tortious interference with contractual relations as a matter of law because the information provided to the third party by defendant was truthful).

B. West-Ward Fails to State a Claim for Tortious Interference with Prospective Economic Advantage.

To state a claim for tortious interference with prospective economic advantage, West-Ward must plead:

“(1) the existence of a protectable economic or contractual right; (2) malicious intent to interfere with such relations; (3) that the defendant’s interference caused

the loss of prospective gain; (4) that such a loss was the proximate cause of injuries.”

DeRobbio v. Harvest Cmty. of Sioux City, Inc., 2002 U.S. Dist. LEXIS 26706, at *21 (D.N.J. Oct. 30, 2002) (dismissing claim for tortious interference with prospective economic advantage under Rule 12(b)(6) for failure to state a claim). West-Ward has failed to allege the existence of a protectable economic right, and therefore its claim should be dismissed under Rule 12(b)(6).

1. West-Ward Fails to Plead a Protectable Economic Right.

a. West-Ward Fails to Specifically Identify any Lost Business Opportunities.

In order to plead the first element of tortious interference with prospective economic advantage—a protectable economic right—West-Ward must allege “either the likelihood of a *particular contract* being actualized, or a *specific business relationship* with which Defendants have interfered.” *Am. Millennium Ins. Co. v. First Keystone Risk Retention Group, Inc.*, 2008 U.S. Dist. LEXIS 19619, at *15 (D.N.J. Mar. 12, 2008) (emphasis added) (granting motion to dismiss tortious interference with prospective economic advantage claim for failure to state a claim); *see also Dana Transp., Inc. v. Ableco Fin., LLC*, 2005 U.S. Dist. LEXIS 18086, at *12 (D.N.J. Aug. 17, 2005) (dismissing tortious interference with prospective economic advantage claim because, “[a]lthough plaintiff’s amended complaint ... discusses so-called third parties, plaintiffs fail to identify the existence of any *specific lost business opportunities*—a necessary element of a tortious interference claim”) (emphasis added); *Coast Cities Truck Sales v. Navistar Int’l Transp. Co.*, 912 F. Supp. 747, 774 (D.N.J. 1995) (“[A] plaintiff must specif[y] some reasonable expectation of economic benefit or, in other words, the existence of a contract or the likelihood that a contract *with a particular party* would have been actualized but for defendant’s wrongful intercession.”) (emphasis added). West-Ward has failed to do so.

As with its tortious interference with contractual relations claim, West-Ward’s tortious interference with prospective economic advantage claim fails to specifically identify a single third party with which Mutual allegedly interfered. The FAC alleges only that West-Ward “had

stable, continuous, and often exclusive business relationships with various purchasers of prescription drugs, including wholesalers, distributors, drug store chains, and pharmacies.” FAC at ¶ 28. It does not allege “the likelihood of a *particular contract* being actualized” (*Am. Millennium Ins. Co.*, 2008 U.S. Dist. LEXIS 19619, at *15), nor does it identify any “*particular party*” (*Coast Cities Truck Sales*, 912 F. Supp. 747, 774) with whom such a contract would have been made. Instead, like the plaintiff in *Dana Transp., Inc.*, West-Ward merely “discusses so-called third parties, [but] fail[s] to identify the existence of any *specific lost business opportunities*.” 2005 U.S. Dist. LEXIS 18086, at *12. For this reason, its claim for tortious interference with prospective economic advantage should be dismissed for failure to state a claim under Rule 12(b)(6).

b. West-Ward’s Past Business Relationships Do Not Establish a Protectable Economic Right.

West-Ward alleges it “had a reasonable expectation ... of obtaining a substantial economic advantage as a result of its longstanding business relationships.” FAC at ¶ 30. However, under New Jersey law, “[t]he mere existence of a long-term business relationship or past business deal is insufficient to establish ‘a protectable economic right’” that can provide the basis for a tortious interference claim. *DeRobbio*, 2002 U.S. Dist. LEXIS 26706, at *21-22; *see also Printing Mart-Morristown v. Sharp Elecs. Corp.*, 116 N.J. 739, 755 (N.J. 1989) (“Printing Mart’s nine-year business relationship would not in itself form the basis of a prospective economic relationship ... [the third party] was always free to find a better printer to do the work.”); *Braunstein v. Benjamin Berman, Inc.*, 1990 U.S. Dist. LEXIS 20922, at *73 (D.N.J. Sept. 12, 1990) (dismissing tortious interference claim because “plaintiffs have not alleged that any of the defendants usurped any contract from them which they would have had with certainty had not the defendants meddled in the plaintiff’s affairs”). West-Ward does “not allege any existing contract, contract negotiations, or invitation to deal” that would create a protectable economic right, and therefore has not established the first element of a claim for tortious interference with prospective economic advantage. *DeRobbio*, 2002 U.S. Dist. LEXIS 26706, at

*22 (dismissing tortious interference with prospective economic advantage claim where plaintiff “merely allege[d] business relationships and an ‘ongoing book of business’”). For this additional reason, West-Ward’s tortious interference with prospective economic advantage claim should be dismissed for failure to state a claim.

C. West-Ward Fails to State a Claim for False Advertising Under the Lanham Act.

In order to state a claim for false advertising under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B), West-Ward must allege:

“1) that the defendant has made false or misleading statements as to his or her own product or another’s; 2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience; 3) that the deception is material in that it is likely to influence purchasing decisions; 4) that the advertised goods traveled in interstate commerce; and 5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of goodwill, etc.”

Syncsort v. Sequential Software, Inc., 50 F. Supp. 2d 318, 340-41 (D.N.J. 1999). Again, West-Ward fails to do so.

1. West-Ward Fails to Allege That Mutual Made any False Statements.

To plead the first element of its false advertising claim, West-Ward must allege that Mutual “ma[de] a commercial message or statement that is either literally false, or literally true but ambiguous such that it has the tendency to deceive consumers.” *Trans USA Prods*, 2008 U.S. Dist. LEXIS 25370, at *12-13 (dismissing claim for false advertising under the Lanham Act for failure to state a claim). West-Ward generally alleges that Mutual made the following false or misleading statements: 1) Mutual’s “COLCRYS tablets are superior to and safer than to [sic] West-Ward’s colchicine tablets”; and 2) “West-Ward’s colchicine tablets are illegal.” FAC at ¶ 49. Neither of these statements are false, nor are they likely to deceive consumers.

First, the FDA has made it a matter of public record that unapproved colchicine tablets such as West-Ward’s (FAC at ¶ 9) are “*not generally recognized as safe and effective for their*

labeled uses.” Exhibit 1, at p. 3; *see also* Exhibit 2, at p. 2. Mutual’s colchicine tablets, on the other hand, *have been approved* by the FDA. FAC at ¶¶ 2, 9. There is nothing literally or impliedly false or misleading about Mutual’s alleged assertion that its FDA approved COLCRYSTM tablets are “superior to and safer than” (FAC at ¶ 49) West-Ward’s unapproved tablets, which the FDA has deemed “not ... safe and effective.” Exhibit 1, at p. 3; *see also* Exhibit 2, at p. 2.

Second, “[g]eneral claims of product superiority are ... deemed an innocuous kind of puffery,” and are not actionable under the Lanham Act. *Syncsort, Inc.*, 50 F. Supp. 2d at 341 (citing *U.S. Healthcare v. Blue Cross of Greater Phila.*, 898 F.2d 914, 926 (3d Cir. 1990) (finding that claim of defendant that it was the better health care plan was non-actionable puffery)). Even if Mutual’s alleged claim that its colchicine tablets are “superior to and safer than [] West-Ward’s colchicine tablets” (FAC at ¶ 49) was literally false—which, as a matter of law, it is not—it would be considered mere puffery, and so could not form the basis for a Lanham Act claim. *U.S. Healthcare*, 898 F.2d at 926.

Third, the FDA has publicly stated that colchicine tablets constitute “a new drug [that] may not be introduced into or delivered for introduction into interstate commerce unless an application is approved by the FDA under either section 505(b) or (j) of the [Food Drug and Cosmetic] Act.” Exhibit 1, at p. 3; *see also* Exhibit 2, at p. 2. Because West-Ward’s colchicine tablets have not been approved by the FDA (FAC at ¶ 9), they are being sold in violation of the FDA’s judgment and the Food Drug and Cosmetic Act. They are therefore *illegal*, and Mutual did not violate the Lanham Act by allegedly alerting relevant consumers to this fact.

Because West-Ward has failed to plead any false statements by Mutual as a matter of law, its claim for false advertising should be dismissed pursuant to Rule 12(b)(6).

2. West-Ward Fails to Alleged any False Statements With the Requisite Specificity.

To the extent the Court finds that West-Ward has alleged false statements by Mutual, West-Ward has failed to do so with the requisite specificity. “[P]leading false advertising under

the Lanham Act requires an intermediate pleading standard which strikes a ‘balance between application and outright rejection of Rule 9(b).’ *Graco, Inc. v. PMC Global, Inc.*, 2009 U.S. Dist. LEXIS 26845, at *84 (D.N.J. Mar. 31, 2009) (citing *Wellness Publ’g v. Barefoot*, 2008 U.S. Dist. LEXIS 1514, at *45-46 (D.N.J. Jan. 8, 2008); *EVCO Tech. & Dev. Co., LLC v. Buck Knives, Inc.*, 2006 U.S. Dist. LEXIS 68549, at *14-15 (E.D. Pa. Sept. 22, 2006); *Trans U.S.A. Prods., Inc.*, 2008 U.S. Dist. LEXIS 25370, at *15 (“Plaintiff must plead its Lanham Act claims with more particularity than traditional notice pleading under *Rule 8* but something less than the specificity of *Rule 9*.”) (emphasis in original).

West-Ward’s vague and general allegations that Mutual is making the false statements that “COLCRYS tablets are superior to and safer than to [sic] West-Ward’s colchicine tablets”; and 2) “West-Ward’s colchicine tablets are illegal” simply do not meet this standard. *See Graco, Inc.*, 2009 U.S. Dist. LEXIS 26845, at *84 (finding that allegations that defendants were making false statements “intended to lead customers to believe that Defendants ... are the successors to [plaintiff’s predecessor in interest] or are [plaintiff’s predecessor in interest]” was found insufficient). West-Ward does not allege who made the statements, when they were made, what specifically was said, and, most importantly to Mutual’s defense, *to whom they were made*.

The only allegation West-Ward makes that could arguably meet this elevated standard is the purported statement of Mutual’s CEO, Dr. Richard Roberts that “[t]he companies pushing out illegal products with no regard for safety issues didn’t add value for patients and doctors that we’ve now created. We’ve revolutionized how colchicine can be used. We don’t compare ourselves to illegal products.” FAC at ¶ 48. That statement does not mention West-Ward or its products at all and cannot serve as the basis for a Lanham Act false advertising claim because it is not a false statement “as to another’s [product].” Indeed, one cannot even tell what illegal product the quote refers to.

Moreover, for the reasons discussed in Section IV(C)(1), *supra*, there is simply nothing false about this statement. The FDA has publicly determined that unapproved colchicine products “may not be introduced into or delivered for introduction into interstate commerce.”

Sunrise Letter at 3; *see also* Concord Letter at 2. Violating this determination and the Food Drug and Cosmetic Act is *illegal*. Mutual, on the other hand, *has* filed the required FDA new drug application and *has* received FDA approval to market its colchicine products. In the process, it discovered new potentially fatal drug-drug interactions and a safer more effective dosing regimen, thereby adding value as Dr. Roberts states.⁷ *See* Exhibit 1, at p. 3; *see also* Exhibit 2, at p. 2.

West-Ward has therefore failed to plead any actionable false statements with the specificity required under the Lanham Act. *Trans U.S.A. Prods., Inc.*, 2008 U.S. Dist. LEXIS 25370, at *15 (dismissing Lanham Act claims for failure to plead with the requisite specificity).

D. West-Ward’s Claim for Unfair Competition Under the Lanham Act Is Entirely Duplicative of Its Claim for False Advertising.

In addition to its claim for false advertising under Section 43(a), West-Ward alleges a Lanham Act claim for unfair competition under the same section. Section 43(a) creates liability for acts of unfair competition *including* false advertising, false “marking,” and passing off. *See* 15 U.S.C. § 1125(a). West-Ward’s Lanham Act unfair competition claim is based on the same allegations of purportedly false or misleading statements (FAC at ¶¶ 58-60) as its Lanham Act false advertising claim—indeed they are almost entirely duplicative of one another. West-Ward has essentially alleged, or attempted to allege, a single Lanham Act claim for “false advertising that resulted in unfair competition.” *See Pactiv Corp. v. Perk-Up, Inc.*, 2009 72796, at *18 (D.N.J. Aug. 18, 2009) (“Defendants allege that Plaintiffs have violated § 43(a) of the Lanham Act by engaging in false advertising that resulted in unfair competition.”) (emphasis added). West-Ward’s Lanham Act claim for unfair competition should therefore be dismissed for the same reasons as, or, in the alternative, should be stricken as duplicative of, its Lanham Act claim for false advertising. *See* Fed. R. Civ. P. 12(f) (“The court may strike from a pleading ... any redundant matter ... on motion by a party.”).

⁷ Furthermore, Dr. Roberts’ statement about “value” is a classic example of non-actionable puffery. *See U.S. Healthcare*, 898 F.2d at 926.

E. West-Ward Fails to State a Claim for Common Law Unfair Competition.

West-Ward's common law unfair competition claim also appears to be entirely based on the same allegedly false and misleading statements as its Lanham Act false advertising claim. However, Federal District Courts sitting in New Jersey have expressly held that allegations of false advertising cannot form the basis for a claim of unfair competition under New Jersey common law. *See, e.g., Wellness Publ'g*, 2008 U.S. Dist. LEXIS 1514, at *62-63 (dismissing common law unfair competition claim based on false advertising because "false advertising claims are not subsumed within the common law tort of unfair competition"). Furthermore, even if false advertising could form the basis of a claim for unfair competition under New Jersey common law, West-Ward's claim would fail because it does not allege any false statements as a matter of law. *See* Section IV(C)(1), *supra*. Therefore, West-Ward's common law unfair competition claim should be dismissed pursuant to Rule 12(b)(6).

V. CONCLUSION

For the foregoing reasons, Mutual respectfully requests that the Court dismiss claims one through five of West-Ward's First Amended Counterclaim, with prejudice, for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6).

Respectfully submitted,

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